Amendment No. 1 to HB1040

<u>Casada</u> Signature of Sponsor

AMEND Senate Bill No. 1258

House Bill No. 1040*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 1, is amended by adding a new part, as follows:

- 63-1-301. For purposes of this part, unless the context requires otherwise:
- (1) "Advanced practice nurse" means any person licensed under title 63, chapter 7, who meets the requirements of §63-7-126.
 - (2) "Department" means the department of health.
 - (3) "Medical doctor" means any person licensed under title 63, chapter 6.
- (4) "Osteopathic physician" means any person licensed under title 63, chapter 9.
- (5) "Pain management clinic" means a privately owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse, and/or a physician assistant provides pain management services to patients, a majority of whom are issued a prescription for, or are dispensed, opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone, for more than ninety (90) days in a twelve-month period; and
- (6) "Physician assistant" means any person licensed under title 63, chapter 19.
- 63-1-302. This part does not apply to:
- (1) A medical or dental school, an osteopathic medical school, a nursing school, a physician assistant program, or an outpatient clinic associated with any of the foregoing schools or programs.

- (2) A hospital as defined in § 68-11-201, including any outpatient facility or clinic of a hospital;
 - (3) Hospice services as defined in § 68-11-201;
 - (4) A nursing home as defined in § 68-11-201;
 - (5) A facility maintained or operated by this state; or
- (6) A hospital or clinic maintained or operated by the federal government. 63-1-303.
- (a) Each licensed health care practitioner who provides services at a pain management clinic shall continue to be regulated only by the board which has issued a license to that practitioner.
- (b) The commissioner of health, in consultation with the board of medical examiners, the board of osteopathic examination, the board of nursing, and the committee on physician assistants, shall promulgate rules necessary to implement this part, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.
- (c) The rules adopted pursuant to subsection (b) may address the following topics, among others:
 - (1) The operation of the clinic;
 - (2) Personnel requirements for the clinic;
 - (3) Training requirements for clinic providers who are regulated by that board:
 - (4) Patient records;
 - (5) Standards to ensure quality of patient care;
 - (6) Infection control;
 - (7) Health and safety requirements;
 - (8) Certificate application and renewal procedures and requirements;
 - (9) Data collection and reporting requirements;

- (10) Inspections and complaint investigations; and
- (11) Patient billing procedures.

63-1-304. Each board shall have the authority to inspect a pain management clinic which utilizes the services of a practitioner licensed by that board. During such inspections, the authorized representatives of the board may inspect all necessary documents and medical records to ensure compliance with this part and all other applicable laws and rules. To the extent possible, the clinic shall be provided reasonable notice prior to the inspection.

63-1-305. Each board shall have the authority to investigate a complaint alleging a violation of this part, or a rule adopted under this part, by a pain management clinic utilizing the services of a health care practitioner licensed by that board. Each board shall also have the authority to investigate a complaint alleging that a facility utilizing the services of a health care practitioner licensed by that board is not properly certified by the department as required by this part.

63-1-306.

- (a) A pain management clinic, as defined in this part, must have a medical director who is a physician that practices in this state under an unrestricted and unencumbered license issued pursuant to § 63-6-201 or § 63-9-104.
- (b) In the event that the medical director, for whatever reason, no longer meets the requirements of this part, the pain management clinic must notify the department, within ten (10) business days, of the identity of another physician who meets the requirements of this part and will act as medical director. A change of majority ownership of a certified pain management clinic requires the submission of a new application for a certificate. Failure to notify the department within ten (10) business days may be the basis for a summary suspension of the clinic's certification.

- (c) Every pain management clinic shall submit an application to the department, on a form prescribed by the department, for a certificate to operate the clinic.
- (d) Each clinic location shall be certified separately regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic.
- (e) The department shall issue a certificate if the department finds that the pain management clinic meets the requirements of this part and that the fee required by the department has been paid.
- (f) If the department finds that a pain management clinic which was issued a certificate no longer meets the requirements of this part, the department shall revoke or suspend the certificate. The pain management clinic shall be entitled to a hearing pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, before revocation or suspension occurs. Further, the department has the discretion to lift the suspension of a certificate when the clinic demonstrates compliance to the department.
- (g) The clinic shall post the certificate in a conspicuous location so as to be clearly visible to patients.
- (h) The department is authorized to charge a fee for the issuance of a certificate.
- (i) The department and each board identified in § 63-1-303(b) shall post on its website an announcement of the requirement that a pain management clinic obtain a certificate from the department, and each board identified in § 63-1-303(b) shall include information about such requirement in a routine communication sent by each board to its licensees.
- (j) A pain management clinic operating on or before the effective date of this act may continue to operate as long as an application for certification is

timely filed within thirty (30) days after the department has published the application form.

- (k) The department shall have the authority to adopt rules, including emergency rules if deemed necessary, to implement the provisions of this part for which the department has responsibility.

 63-1-307.
- (a) A certificate issued under this part expires on the second anniversary of the date it is issued.
- (b) The department may grant to a pain management clinic a ninety-day grace period from the expiration date of its certificate to renew the certificate.
- (c) No pain management clinic whose certificate has expired may continue to operate or provide pain management services following the expiration of the grace period.

63-1-308.

- (a) A pain management clinic may apply to renew its certificate by:
- (1) Submitting a renewal application to the department on the form and in a time frame prescribed by the department; and
 - (2) Complying with any other requirements of the department.
- (b) If a certificate is not renewed before the expiration of the grace period,the clinic must reapply for a new certificate to operate the clinic and is notauthorized to operate while such new certificate application is pending.63-1-309.

(a)

(1) In the application for a certificate or within ten (10) days of the occurrence of any of the events listed in (A) – (C) below, a pain management clinic shall disclose whether any person who owns, co-owns or operates, or otherwise provides services in the clinic, an employee of the clinic, or a person with whom the clinic contracts for services:

- (A) Has ever been denied, by any jurisdiction, a license under which the person may prescribe, dispense, administer, supply, or sell a controlled substance;
- (B) Has ever held a license issued by any jurisdiction, under which the person may prescribe, dispense, administer, supply, or sell a controlled substance, that has been restricted; or
- (C) Has ever been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance.
- (2) The department may deny a certificate or renewal of a certificate to a pain management clinic under any of the circumstances listed in subdivision (a)(1).
- (b) A pain management clinic may not be owned wholly or partly by a person who has been convicted of, pled nolo contendere to, or received deferred adjudication for:
 - (1) An offense that constitutes a felony; or
 - (2) An offense that constitutes a misdemeanor, the facts of which relate to the distribution of illegal prescription drugs or a controlled substance as defined in § 39-17-402.
- (c) If any practitioner providing services at a pain management clinic dispenses or prescribes more than a seventy-two hour dose of controlled substances for the treatment of chronic nonmalignant pain, the practitioner must document in the patient's record the reason for prescribing or dispensing that quantity.
- (d) A medical director shall be on-site at least twenty percent (20%) of the clinic's weekly total number of operating hours.

63-1-310.

- (a) A pain management clinic may accept only a check, credit card or money order in payment for services provided at the clinic, except as provided in § 63-1-310(b).
- (b) A payment may be made in cash for a co-pay, coinsurance or deductible when the remainder of the charge for the services will be submitted to the patient's insurance plan for reimbursement.

 63-1-311.
- (a) A violation of this part, or a rule adopted under this part, is grounds for disciplinary action against a practitioner providing services at a pain management clinic certified under this part by the board which licensed that practitioner.
- (b) A practitioner who provides pain management services at an uncertified pain management clinic is subject to an administrative penalty of one thousand dollars (\$1,000) per day, imposed by the board which licensed that practitioner, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. Before such a penalty may be assessed by the board, the board shall give at least thirty (30) days notice to the practitioner of the alleged violation of this part.

SECTION 2. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end, the provisions of this act are declared to be severable.

SECTION 3. For purposes of promulgating rules, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect on January 1, 2012.